510(K) SUMMARY

K130310: Certain® BellaTek™ Provisional Abutment

JUN 2 1 2013

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR §807.92

Submitter Information	
Name	BIOMET 3i™
Address	4555 Riverside Drive Palm Beach Gardens, Florida 33410
Phone number	(561) 776-6840
Fax number	(561) 514-6316
Establishment Registration Number	1038806
Name of contact person	Jacquelyn A. Hughes, RAC
Date prepared	February 1, 2013
Name of Device	
Trade or proprietary name	Certain® BellaTek™ Provisional Abutment
Common or usual name	Dental Abutments
Submission Information	
Classification name	Endosseous Dental Implant Abutment
Classification panel	Dental
Regulation	21CFR §872.3630
Product Code(s)	NHA
Legally marketed device(s) to which equivalence is claimed	K072642 BIOMET**3i**™ Dental Abutments and Restorative Components K071551 QuickBridge® Cylinder and Cap K061177 PROVIDE® Temporary Cylinder K060291 PreFormance® Temporary Cylinder
Reason for 510(k) submission	Addition to BIOMET 3i™ abutment product line to include a two piece temporary provisional healing abutment (cylinder and cap) that will support a single prosthesis and will incorporate the Encode® impression system.
Device description	The Certain® BellaTek™ Provisional Abutment is a two piece temporary healing abutment that consists of a machined provisional titanium alloy (6AL-4V) post, a PEEK provisional cap, and a machined stainless steel (316L) retaining screw with gold plating.
Intended use of the device	The Certain® BellaTek™ Provisional Abutment is intended for use in the anterior and posterior areas of the mouth.
Indications for use	Provisional Abutments are intended for use as an accessory to endosseous dental implants to support a prosthetic device in a partially or fully edentulous patient. They are intended for use to support a prosthesis in the mandible or maxilla for up to 180 days during endosseous and gingival healing, and are for non occlusal loading of provisional restorations. The prosthesis will be mechanically retained to the abutment system.

510(K) SUMMARY
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Summary of the technological characteristics of the device compared to the predicate					
Characteristic	**New Device**	**K060291**	**K072642**	**K071551**	**K061177**
Abutment Post					
Material	Titanium Alloy /ASTM F136	Titanium Alloy /ASTM F136 and PEEK/ASTM F2026	Titanium Alloy /ASTM F136	Titanium Alloy /ASTM F136	Titanium Alloy /ASTM F136
Surface Modifications	Titanium Nitride Coated Anodized	N/A	Laser marking on Abutment Post	N/A	Anodized
Abutment Height	5.44mm Abutment with Cap 6mm	12mm (can be prepped to desired height)	3, 4, 6, 8mm	5.8mm	5, 6, 7, 8, 9mm
Emergence Profile	3.6mm, 4.5mm, 5.5mm	4.0, 5.0, 5.6, 6.6mm	3.8, 4.1, 5.0, 5.6, 6.0, 7.5mm	4.8mm	4.8, 6.5mm
Platform Diameter	3.4, 4.1, 5.0mm	3.4, 4.1, 5.0, 6.0mm	3.4, 4.1, 5.0, 6.0mm	4.8mm	4.1, 5.0, 6.0mm
Collar Height	2mm	1.5mm	Varies depending on size (ranges from 0.25mm to 9.1mm)	1.5mm	1, 2, 3, 4mm
Design	Single unit	Single Unit/ Multi-Unit	Single unit	Multi-unit	Single unit
Type	Abutment and cap system	Cylinder that can be prepped	Abutment only	Cylinder and cap system	Abutment and temporary cylinder option
Occlusal Loading	Non-occlusal	Nonocclusal	Nonocclusal	Non-occlusal	Non-occlusal
Abutment retention to implant	Screw	Screw	Screw	N/A – part of multi construct	Screw
Connection to implant	Internal	Internal External	Internal External	N/A – part of multi construct	Internal
Abutment Cap					
Material	Polyetheretherketone (PEEK)/ ASTM F2026	N/A	N/A	Polyetheretherketone (PEEK)/ ASTM F2026	Polyetheretherketone (PEEK)/ ASTM F2026
Surface Finish	Internal	Internal External	Internal External	N/A – part of multi construct	Internal
Cap Height	4.0mm	N/A	N/A	5.1mm	6.5mm
Cap Margin Diameter	4.0mm, 4.9mm, 5.9mm	N/A	N/A	4.8mm	4.8, 6.5mm
Shape	Conical	N/A	N/A	Conical	Conical
Retention to abutment	Snap	N/A	N/A	Snap/ cement	Cemented

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Summary of the technological characteristics of the device compared to the predicate					
Characteristic	**New Device**	**K060291**	**K072642**	**K071551**	**K061177**
Retention to prosthesis (crown)	Mechanical	N/A	N/A	Mechanical	Mechanical/ cement

Performance Data		
Summary of Non-Clinical Tests Conducted for Determination of Substantial Equivalence		
Performance Test Summary-New Device		
Characteristic	Standard/Test/FDA Guidance	Results Summary
Static Bend	ISO 14801	Passed
Fatigue	ISO 14801	Passed
Snap on/off Force Testing		Passed
Screw Torque		Passed

Comparative Performance Information Summary			
Characteristic	Requirement	New Device	Predicate Device
Static Bend/ Fatigue	ISO 14801	Exceeds	K060291

Summary of Clinical Tests Conducted for Determination of Substantial Equivalence and/or of Clinical Information
Clinical Performance Data/Information: N/A
Conclusions Drawn from Non-Clinical and Clinical Data
No clinical testing was necessary for a determination of substantial equivalence. The results of mechanical testing indicated the devices performed within the intended use, did not raise any new safety and efficacy issues and were found to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 21, 2013

Ms. Jacquelyn A. Hughes
Director, Regulatory Affairs & Clinical Research
BIOMET 3i
4555 Riverside Drive
PALM BEACH GARDENS, FL 33410

Re: K130310
Trade/Device Name: Certain® BellaTek™ Provisional Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: May 20, 2013
Received: May 23, 2013

Dear Ms. Hughes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's *Office* of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner DDS, MA Mary S. Runner -S

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K130310

Device Name: Certain® BellaTek™ Provisional Abutment

Indications for Use:

Provisional Abutments are intended for use as an accessory to endosseous dental implants to support a prosthetic device in a partially or fully edentulous patient. They are intended for use to support a prosthesis in the mandible or maxilla for up to 180 days during endosseous and gingival healing, and are for non occlusal loading of provisional restorations. The prosthesis will be mechanically retained to the abutment system.

Prescription Use __X__ AND/OR Over-The-Counter Use __NO__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
2013.06.21 13:27:16 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K130310